REMARKS / ARGUMENTS

Claims 1-19 are pending in this application.

Applicant's representative would like to thank the examiner for discussing this case via a telephone interview on July 25, 2003. In the interview, the applicant's representative and the examiner discussed the interrelationship of co-pending applications 09/958,050 ("the '050 application); 10/066,964 ("the '964 application); 10/067,020 ("the '020 application"); 10/067,010 ("the '010 application"); 10/066,836 ("the 964 application"); 10/200,364 ("the '364 application"); 10/281,735 ("the '735 application") and 10/241,658 ("the '658 application"), and 10/066,951 ("the '951 application") and US Patent 6,537,983 ("the 983 Patent").

Applicant has included herewith an information disclosure statement and Form 1449 listing the co-pending applications, as well the '983 Patent. Also included in the IDS are a list of references cited in a PCT Search Report recently issued in a foreign counterpart to this application.

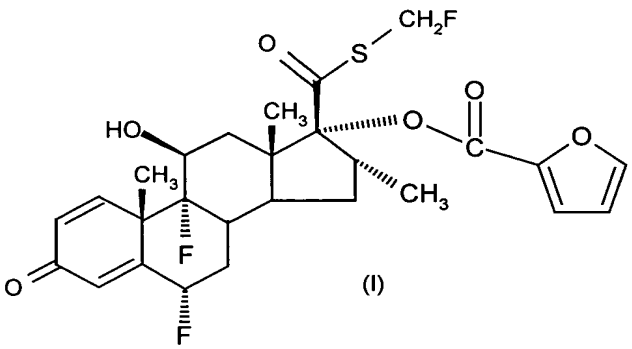
In the June 3, 2003 Official Action, claims 1-19 were rejected under 35 USC 101, for double patenting over claims 18, 22 and 23 of the '050 application, and for obviousness-type double patenting over the '050, '951, '836, '020; '364, '658, '010, and '735 applications and the '983 Patent.

No rejections were indicated based upon the prior art of record.

No "Same Invention" Double Patenting Is Present:

The claims of the present application are directed to an HFA formulation wherein the compound of formula (I) or a solvate thereof is completely dissolved in the liquid HFA propellant. Independent Claim 1, the sole independent claim of the present application, recites:

1. A pharmaceutical aerosol formulation comprising (i) a compound of formula (I)



(I)

or a solvate thereof as medicament, (ii) a liquified hydrofluoroalkane (HFA) gas as propellant; and characterised in that the compound of formula (I) or a solvate thereof is completely dissolved in the formulation.

In contrast to this, the claims of pending 09/958,050 are directed to an invention that differs in scope to the present invention as Claim 18 encompasses systems where the compound of formula (I) is presented as a suspension as well as a solution. Specifically, Claim 18 recites:

> A pharmaceutical aerosol formulation comprising a compound of formula (I), or a physiologically acceptable solvate thereof, and a fluorocarbon or hydrogen-containing fluorocarbon as propellant, optionally in combination with a surfactant and or a co-solvent.

Claim 22 specifies two specific HFA propellants, and Claim 23 relates to a pharmaceutical aerosol formulation optionally further comprising another therapeutically effective agent, and two specific HFA propellants.

According to MPEP 804 II.A one test for double patenting under 35 USC 101 asks: "*Is there an embodiment of the invention that falls within the scope of one claim, but not the other? If there is such an embodiment, then identical subject matter is not defined by both claims and statutory double patenting would not exist.*" *For example,*

the invention defined by a claim reciting a compound having a "halogen" substituent is not identical to or substantively the same as a claim reciting the same compound except having a "chlorine" substituent in place of the halogen because "halogen" is broader than "chlorine". " (MPEP, p. 800-20, August 2001). (emphasis added).

Applying this test, it is apparent that no statutory type double patenting issue is presented by these claims, as in embodiment comprising:

> *an aerosol formulation containing a compound of formula (I) in the HFA propellant, 1,1,1,2-tetrafluoroethane, wherein the compound of formula I is suspended in the HFA propellant*

the embodiment falls within the literal scope of claims 18, 22 and 23 of the '050 application, but not within the literal scope of the claims of the present application, which requires the compound of formula I to be completely dissolved in the formulation. Like the "halogen" and "chlorine" example used in the MPEP, the presence of a this embodiment indicates that identical or substantively the same subject matter is not recited in the claims of both patents, and "statutory double patenting would not exist." Withdrawal of the 101 statutory type double patenting rejection is therefor respectfully requested.

The Obviousness-type Double Patenting Issues Have Been Resolved

In the June 3, 2003 Official Action, claims 1-19 were rejected for obviousness-type double patenting over the '050, '951, '836, '020, '364, '658, '010 and '735 applications and the '983 patent. In the telephone interview, the examiner agreed to withdraw the "obviousness-type" double patenting rejections based on the '020, '010, '364, '658, '836, and '735 applications. The obviousness-type double patenting assertion with regard to the aqueous solution claims of '951 was not discussed, and the applicant and examiner failed to reach agreement concerning the '050 application and the '983 Patent.

Rather than more fully debate this issue on the claims of the '050 application and '983 patent, and in an effort to avoid the necessity of discussions over the '951 application, the applicant's representative and the examiner agreed that the need for further discussions on this issue could be obviated through the filing of a terminal disclaimer. Therefore, enclosed herewith are terminal disclaimers concerning US Serial Nos. 09/958,050 and 10/066,951 and US Patent No. 6,537,983.

As a matter of record, applicant respectfully asserts that the instant claims are not obvious over the claims of the disclaimed patents/applications, and no obviousness-type double patenting is presented. The claims of this application are patentably distinct over the claims in each of the other references, as being directed to different subject matter. Applicant has submitted the terminal disclaimers requested by the examiner solely in an effort to further prosecution, and without prejudice. The disclaimers have no effect on the actual term of any patent resulting from this application, as patents resulting from each of the disclaimed cases would have expire on the same date as a patent issuing from this application, even in the absence of the disclaimer. In filing these disclaimers, applicant specifically reserves the right to address any double patenting issues in the future, should the need arise. Applicant makes particular note of MPEP 804.02 II and established case law findings of the Federal Circuit, in Quad Environmental Technologies v. Union Sanitary District, 946 F.2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991), that the filing of a terminal disclaimer to obviate a rejection based on a non-statutory double patenting is not an admission of the propriety of the rejection. The filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection.

Amendment of Specification to Clarify Relation of Filings

The first paragraph of the specification has been amended to clarify the lineage of the present application.

As all issues raised by the examiner in the Official Action and telephone interview have been addressed, applicants respectfully assert that the pending claims are

inventive and are in a condition for allowance. Applicant requests that a timely Notice of Allowance be issued in this case. If any matters exist that preclude issuance of a Notice of Allowance, the examiner is requested to contact the applicant's representative at the number indicated below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge any fees or credit any overpayment, particularly including any fees required under 37 CFR Sections 1.16 and/or 1.17, and any necessary extension of time fees, to deposit Account No. 07-1392.

Respectfully submitted,

Dated: 31 July 2003

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